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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,499	01/06/1999	ROGER M. LORIA		2403

7590 10/06/2003

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EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/225,499

Applicant(s)

LORIA, ROGER M.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The allowance of claim 15-18 is herein withdrawn in view of the following rejection.

Claims 15-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific tumor disclosed, does not reasonably provide enablement for the term "tumors". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "tumors" in claims 15-20 and 22-24 lacks clear exemplary support in the specification as filed.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary all of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: claims 15-20 and 22-24 are drawn to treating tumors broadly.

Breadth of the claims: the complex nature of the claim greatly exacerbated by breadth of the claims. The claims encompass treating tumors broadly.

Guidance of the specification:

The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treating tumors broadly. The guidance provide by

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the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples; all the working examples provided by the specification are directed to specific cancers.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to single agent for treating cancer or tumors broadly is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (see pages 362-365 of Carter et al reference).

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers or tumors in a mammal subject with the claimed compounds makes practicing the claimed invention unpredictable.

The quantity of experimentation necessary:

Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows data on twenty-three types of cancer. Applicants should at least test these types of cancer with the claimed anticancer agent.

Moreover, the Segaloff publication filed with paper no. 28 states on page 811, col. 2, line 7 to page 812, col. 1, line 3 states that " we can produce further changes in

the testosterone molecule. If the 17B hydroxyl is changed to the α position...; this interfered tremendously in the androgenicity and clinical effectiveness (fig. 5,C)".

Therefore, one skilled in this art would not employ the 17 α hydroxyl for treating breast cancer.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd
September 22, 2003



JEROME D. GOLDBERG
PRIMARY EXAMINER